Compliance Assistance Tool for Clean Air Act Regulations: Subpart GGG of40 CFR NESHAPS for Source Category Pharmaceutical Production

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Chapter 4
Requirements for Storage Tanks

4.1 Overview

The pharmaceutical MACT standards provide several options for standards for HAP emissions from certain storage tanks (raw material tanks and certain tanks storing materials destined for recovery) that exceed a specific size and vapor pressure cut-off. The standards options are expressed as either percent reduction, TOC limit at the control device outlet, technology installation (floating roof), or vapor balancing. Alternatively, owners may elect to take advantage of a pollution prevention option that aims to reduce emissions by reducing the amount of HAP-containing materials used at the facility rather than installing end-of-pipe emissions controls. In some instances, owners can use emissions averaging to achieve emissions reductions. Existing sources must comply with the standards by October 21, 2002; in general, new sources must be in compliance immediately upon start-up, or by August 29, 2000, whichever is later. For some new sources, or reconstructed sources, the exact compliance date may depend on when construction or reconstruction commences, if there are stringency differences between the final amendments and/or the draft amendments or the final rule. Please refer to the chart on page 3-14.

The initial compliance demonstration for tanks is done through a performance test or a design evaluation of those complying with the percent reduction or TOC limit. For those complying with the floating roof option, the initial compliance demonstration is done through visual inspections of the roof. Thereafter, owners will confirm continued compliance through monitoring, recordkeeping, inspection and reporting activities.

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4.2 Structure of the Regulation

Major components of the regulations are illustrated in the flow diagram 4-1. Regulatory citations are provided within the flow diagram. The standards for storage tanks are given in the regulations at §63.1253. The compliance procedures for demonstrating initial compliance are at §63.1257(c). Monitoring requirements are in §63.1258. Recordkeeping and reporting requirements are found at §63.1259 and §63.1260, respectively. Readers are referred to **$ Chapter 13 - Reporting** for information on what must be included in a facility's Initial Notification, Precompliance

Report, Notification of Compliance Status Report, and Periodic Reports.

How Do I Know if My Tanks are Subject to Regulation?

4.3 Applicability

Four criteria define the storage tanks subject to substantive provisions of the MACT standards:

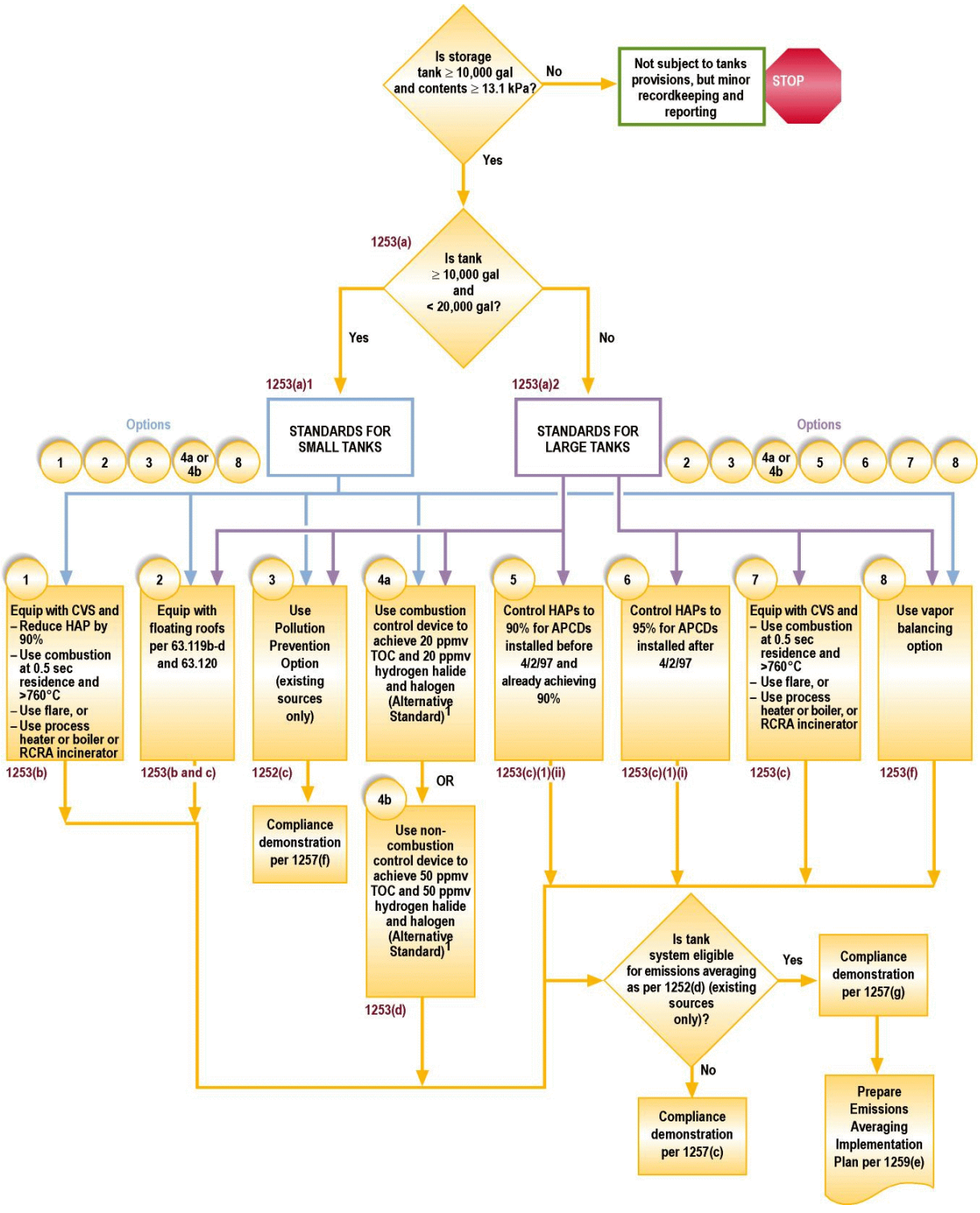
- Storage tanks or vessels that store organic HAP-containing materials (raw material feedstocks or used solvent for the purpose of solvent recovery), AND
- Have storage capacity of at least $38m^3$ (approximately 10,000 gallons), AND
- Store materials with a total HAP maximum true vapor pressure greater than or equal to 13.1 kPa (1.9 psia), AND
- The storage tank is part of a PMPU subject to the MACT. (For a discussion of assigning "ownership" to tanks, refer to pages 3-10 of this document and/or §63.1250(e).

A number of tanks and storage vessels are NOT considered storage tanks:

- Vessels permanently attached to motor vehicles such as trucks, railcars, barges, or ships
- Pressure vessels designed to operate at pressures greater than 204.9 kPa (30 psia), and without emissions to the atmosphere
- Vessels storing organic liquids that contain HAP only as impurities
- Wastewater storage tanks
- Process tanks, which are defined as tanks that are used to collect material discharged from a feedstock storage tank or unit operation and transfer this material to another unit operation within the process or a product storage tank. Surge control vessels and bottoms receivers that fit these conditions are considered process tanks. Process tanks include product tanks and isolated intermediate tanks.

IMPORTANT NOTE: Product and isolated intermediate tanks are process tanks and are part of the PMPU that produced the stored materials. Vents from these product tanks are therefore considered process vents.

IMPORTANT NOTE: Storage tanks at pharmaceutical manufacturing operations that do not meet the four criteria above are still subject to minor recordkeeping and reporting requirements. All applicability determinations must be reported in the Initial Notification of Compliance status report, per §63.1260(f)(1).



[1]As an option for the alternative standard, owner/operator may control post-combustion device HCl emissions by 95% in lieu of achieving 20 ppmv hydrogen halide and halogen emissions.

Figure 4-1. Subpart GGG Storage Tanks, Applicability and Standards

Q and A

Q. ***Is there an emissions cut-off, under which the standards for tanks do not apply?***

A. *No; the standards apply regardless of the emissions level. There is no emissions-based applicability cut-off.*

Q. ***Are so-called "day tanks," which are used to store HAP-containing liquids temporarily, considered "storage tanks," and therefore subject to the MACT regulations?***

A. *Day tanks are considered part of the PMPU with which they are associated. Day tanks meet the definition of process tank - a tank that is used to collect material discharged from a feedstock storage tank or unit operation and transfer this material to another unit operation or a product storage tank. As such, emissions from day tanks that meet the definition of process tanks will be subject to process vent regulations rather than the storage tanks requirements.*

Q. ***Are tanks that are used to store recovered solvents regulated as storage tanks under the MACT standards?***

A. *It depends on the process:*

- If recovered solvent is accumulated from multiple batches, the tank is considered a storage tank.

-The tank receives recovered material from one or more unit operations in the same process or batch (e.g., a distillation overhead receiver) and sends it to one or more unit operations (e.g., a reactor within the same process or batch), the tank is a step in the process, and therefore considered a process tank rather than a storage tank.

Q. ***If a tank holds a mixture of HAP-containing materials, how is the vapor pressure calculated?***

A. *The regulations define "maximum true vapor pressure" as the equilibrium partial pressure exerted by the total organic HAP in the liquid 1) at the temperature equal to the highest calendar-month average of the storage or transfer temperature, for liquids stored or transferred* ***above or below the ambient temperature*** *or 2) at the local maximum monthly average temperature as reported by the National Weather Service, for liquids stored or transferred* ***at the ambient temperature****. The definition also refers to methods to be used in calculating vapor pressure: API publication 2517 (Evaporative Loss From External Floating-Roof Tanks - incorporated by reference at 63.14); standard reference texts; ASTM Method D2879-97 (incorporated by reference at 63.14) or; any other method approved by the Administrator.*

What are the Regulatory Standards for My Tanks?

4.4 Standards

The regulations specify standards options according to the size of the tank. Many, but not all, of the standards options are the same for "small" and "large" tanks.

In the table below, the differences in standards for small versus large tanks are shown in bolded print. Please note that there is **no distinction between new and existing tanks with regard to standards, except that new tanks cannot use P2 or emissions averaging and existing tanks may qualify for grandfathered control levels.**

Vapor Pressure ≥ 13.1 kPa (1.9 psia)	
"small tanks" 38m³# tank < 75m³ (10,000 gal) (20,000 gal)	**"large tanks" tank $ 75m³ (20,000 gal)**
STANDARDS OPTIONS: 1. Fixed roof with internal floating roof 2. External floating roof 3. External floating roof converted to internal floating roof 4. Closed vent system with device that **reduces inlet emissions of total HAP by 90%** or achieves 20 ppmv TOC and 20 ppmv halogen outlet limit 5. Closed vent system with enclosed combustion device that has minimum residence time of 0.5 seconds at 760 EC 6. Closed vent system with flare that meets the requirements of §63.11(b) 7. Closed vent system vented to a boiler, process heater, or incinerator, as described in §63.1257(a)(4) 8. Alternative Standard - Combustion control device that achieves outlet concentration of 20 ppmv or less TOC (as calibrated on methane or the predominant HAP) and 20 ppmv or less hydrogen halides and halogens.[1] (If emissions are routed to a noncombustion control device, outlet TOC concentration of 50 ppmv must be achieved, and 50 ppmv hydrogen halides/halogens.) 9. Vapor balancing, pollution prevention, and emissions averaging options - see below	STANDARDS OPTIONS: 1. Fixed roof with internal floating roof 2. External floating roof 3. External floating roof converted to internal floating roof 4. Closed vent system with device that **reduces inlet emissions of total HAP by 95% *** or achieves 20 ppmv TOC and 20 ppmv halogen outlet limit 5. Closed vent system with enclosed combustion device that has minimum residence time of 0.5 seconds at 760 EC 6. Closed vent system with flare that meets the requirements of §63.11(b) 7. Closed vent system vented to a boiler, process heater, or incinerator, as described in §63.1257(a)(4) 8. Alternative Standard - Combustion control device that achieves outlet concentration of 20 ppmv or less TOC (as calibrated on methane or the predominant HAP) and 20 ppmv or less hydrogen halides and halogens.[1] (If emissions are routed to a noncombustion control device, outlet TOC concentration of 50 ppmv must be achieved, and 50 ppmv hydrogen halides/halogens.) 9. Vapor balancing, pollution prevention, and emissions averaging options - see below

***** If a tank already is equipped before April 2, 1997, with a device that is designed to reduce emissions by 90-95%, the owner/operator is required to achieve 90% reduction (i.e., not required to achieve the additional 5% increment).
1. As an option for the alternative standard, the owner/operator may control post combustion device HCl emissions by 95% in lieu of achieving 20 ppmv hydrogen halide and halogen emissions.

The standards do not apply during periods of planned routine maintenance of the control devices. These periods of planned routine maintenance cannot exceed 240 hours per year.

It may be possible to have a facility that chooses to use several standards options concurrently. For example, an owner or operator may choose to use the 20 ppm TOC standard for a group of tanks whose emissions are routed to a central control device, but use the 90% reduction standard for other tanks not vented to the central control device. These decisions regarding control options will depend on the configuration of processes and tanks at the facility.

Vapor Balancing Option

The final rule contains a vapor balancing option for new and existing sources. The vapor balancing system must meet several criteria:

- The system must be designed and operated to route vapors from the tank to the railcar or tank truck from which the storage tank is filled.
- The tank cars and railcars must have a current DOT pressure test certification (49 CFR Part 180 for tank trucks; 49 CFR 173.31 for railcars).
- Unloading can occur only when the railcar's/tank truck's vapor collection system is connected to the tank's vapor collection system.
- Pressure relief devices on the tank truck, railcar, or storage tank should not open during loading or as a result of diurnal temperature changes (i.e., there should be no breathing losses).
- The pressure relief devices on storage tanks must be set to no less than 2.5 psig at all times to prevent breathing losses.
- During cleaning or reloading, railcars/tank trucks must either: (1) be connected to a closed vent system with a control device that reduces inlet emissions of HAP by 90 % weight or greater, or (2) have a system that routes the displaced vapors from reloading back to the tank from which the liquid being transferred originated. The owner/operator of the facility where the railcar/tank truck is reloaded or cleaned must submit a certification to the storage tank owner, certifying that the system will meet (1) or (2). The certifying facility may however revoke certification by sending a written statement to the tank owner, giving him/her 90 days notice that the facility will no longer accept responsibility for complying with (1) or (2).

What is the Pollution Prevention Option?

In lieu of the tank standards discussed above, an owner or operator (O/O) with existing storage tanks can choose to meet pollution prevention (P2) standards for the PMPU. The P2 requirements are either:

- reduce the production-indexed HAP consumption factor (lb HAP consumed/lb of product produced) by 75% from a specified baseline average established no earlier than 1987, or
- reduce the production-indexed HAP consumption factor by 50% from a specified baseline average established no earlier than 1987 AND reduce total PMPU HAP emissions divided by the annual production rate (lb HAP emitted per

year/lb produced per year) to a value greater than 25% of the baseline production-indexed consumption factor (i.e., achieve 50% reduction by using pollution prevention and achieve additional 25% by using add-on control devices). For more information on the pollution prevention option, see ° **Chapter 10 - Pollution Prevention Alternative.**

4.5 Emissions Averaging

The MACT rule includes provisions for **emissions averaging** for tanks. In some cases, it may be advisable for an owner to use emissions averaging when attempting to demonstrate compliance with the emission reduction standards. There are some restrictions:

- Some states may not allow emissions averaging,
- Only existing tanks may be included in an averaging group,
- Large tanks (greater than 20,000 gal capacity) that are already achieving a 90-95% reduction prior to 4/2/97 cannot be included (i.e. tanks complying with 1253(c)(1)(ii)),
- Storage tanks permanently taken out of HAP service cannot be included,
- Tanks already controlled on or before 11/15/90 cannot be included unless the level of control is increased after 11/15/90,
- Tanks already subject to control because of another State or Federal rule cannot be included, unless the level of control is increased above what is required by the other State or Federal rule, and
- No more than 20 tanks can be included in an averaging group.

Owners or operators interested in finding out more about using emissions averaging should refer to $ **Chapter 11 - Emissions Averaging for Process Vents and Storage Tanks.**

How do I Demonstrate Initial Compliance with the Regulatory Standard?

4.6 Initial Compliance Demonstration

Documentation proving initial compliance is required. The exact nature of the demonstration depends on the standard chosen by the owner or operator - percent reduction, add-on device achieving 20 ppm TOC (or 50 ppm if noncombustion device), other specific control device, floating roof, or vapor balancing. The initial compliance demonstrations are very important in that the operating parameters that are established during the compliance demonstration will be monitored later to confirm on-going compliance, if complying with the percent reduction or outlet concentration standard. The table shown on the next page describes the general compliance demonstration procedures according to the standard the owner/operator is trying to achieve.

The reader is referred to ° **Chapter 8 - Compliance Demonstrations and Testing Procedures**, for detailed instructions on conducting initial compliance demonstrations using design evaluations, performance testing, or TOC measurements (for alternative standard).

INITIAL COMPLIANCE DEMONSTRATION*	
If the regulatory standard used is....	**To demonstrate initial compliance, must...**
Floating roof	conduct compliance demonstration according to HON regulations (see section on Floating Roof Demonstration)
Percent reduction (either 90% or 95%)	either do a design evaluation or conduct performance testing of control device
Outlet concentration limit (20 ppmv TOC)	conduct performance test
Flares	meet standards of 63.11(b)
Closed vent system with combustion device (0.5 seconds residence time at 760 EC)	prepare design evaluation that documents residence time and temperature
Process heater or boiler as described in 63.1257(a)(4)	exempt from compliance demonstration
20 ppmv TOC or 50 ppmv TOC if noncombustion (alternative standard)	conduct CEM monitoring** that demonstrates outlet TOC is 20 ppmv or less, and outlet hydrogen halide and halogen concentration is 20 ppmv or less, or 50 ppmv if noncombustion device
Vapor balancing	the owner/operator of the reloading/cleaning facility must either do a design evaluation or conduct performance testing on the control device to show that it achieves 90% reduction, if an add-on control device is being used. Certification from railcar or tank truck owner that they will comply with applicable standards. Send certification to facility and Administrator. Design evaluation or performance testing is not required if the reloading/cleaning facility also does vapor balancing at their facility.

*A separate compliance demonstration for tanks is not necessary if the tanks' emissions are routed to a control device being used for process vents, and a compliance demonstration will be done in accordance with the process vent regulations.

**CEM monitoring is not always required for hydrogen halide and halogen (see 63.1258(b)(5)(i)(c) and (d).

If I Choose to Meet the Standard by Installing a Floating Roof, What Must I do to Demonstrate Compliance?

Floating Roof Demonstration

The floating roof demonstration required under the pharmaceutical MACT rule is the same as that required under the HON regulations at 63.119(b)-(d) (engineering specifications) and 63.120 (monitoring provisions).

Some practical wording changes in the referenced HON regulations are necessary:

Terminology in HON	What it means in pharm. MACT
"storage vessel"	"storage tank" as used in §63.1250
"December 31, 1992"	"April 2, 1997"
"April 22, 1994"	"September 21, 1998"
"compliance date specified in §63.100"	"compliance date specified in §63.1251"
"maximum true vapor pressure of the total organic HAP's in the stored liquid falls below the values defining Group 1 storage vessels specified in table 5 or table 6 or this subpart"	"maximum true vapor pressure of the total organic HAP in the stored liquid falls below 13.1 kPa (1.9 psia)"

Owners and operators who plan to use floating roofs to comply with the emissions standards should refer to $ guidance materials developed for the HON rule: *HON Inspection Tool - EPA-305-B-97-006, September, 1997.* In particular, see Control Techniques Specific to Storage Vessels - Floating Roof Vessels (Section 6.4.2), Storage Vessel Control Requirements (Section 7.3.3), and Storage Vessel Testing, Monitoring, Recordkeeping, and Reporting (Section 7.3.4).

What On-Going Monitoring is Required (After the Initial Compliance Demonstration) to Confirm That My Tanks are Still in Compliance With the Standards?

4.7 Monitoring On-Going Compliance for Tanks Complying with the Percent Reduction Standard

Owners or operators of affected sources are required to regularly monitor the relevant control devices used to achieve the emissions control standards to confirm on-going compliance with the standards.

During the initial compliance demonstration, owners or operators establish maximum or minimum operating parameter(s). Information from any performance testing, calculations, or design evaluations is used to establish the operating parameter(s). The specific operating parameters which must be monitored regularly will depend on the control devices being used.

The reader is referred to ° **Chapter 9 - Monitoring** for a detailed discussion of establishing monitoring parameters and conducting monitoring.

IMPORTANT NOTE: Owners/operators of control devices that control **less than 1 ton/yr HAP emissions**, before control, are not required to conduct monitoring other than to verify daily that the device is working properly. If the control device is used to control batch processes as well as tank emissions, the verification may be on a per batch basis. The owner/operator must determine how the verification process is to be conducted. The steps that the owner or operator will follow in conducting these demonstrations must be described in the Precompliance Report to be submitted 6 months prior to the compliance date.